LITE DEPALMA GREENBERG, LLC
Allyn Z. Lite
Michael E. Patunas
Mayra V. Tarantino
Two Gateway Center, 12th Floor
Newark, New Jersey 07102
Telephone: (973) 623-3000
Facsimile: (973) 877-3872
alite@litedepalma.com
mpatunas@litedepalma.com
mtaratino@litedepalma.com

Attorneys for Defendants Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

IN THE UNITED STATES DISTRICT COURT
THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 3:11-CV-00760-JAP-TJB Motion Date: November 19, 2012

HANMI'S REPLY IN SUPPORT OF ITS MOTION TO AMEND ITS CONTENTIONS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Defendants Hamni USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. (collectively "Hanmi"), respectfully submit this Reply in Support of Hanmi's October 15, 2012 Motion to Amend Its Contentions (D.I. 238, 238-1, 239). Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively "AstraZeneca") filed their Response to Hanmi's Motion on November 7, 2012 (D.I. 244).

I. AstraZeneca's Response Is A Transparent Attempt To Alter The Trial Schedule

At page 1 of its Response, second paragraph (D.I. 244), AstraZeneca concedes that it really does not oppose the merits of Hanmi's motion, but instead reveals its true motive of delay of the trial schedule. Because AstraZeneca's primary position is that it does not oppose the merits, Hanmi's motion should be granted for the reasons set forth therein. However, granting the motion should not be conditioned on delay of the case schedule, because AstraZeneca's assertions that Hanmi's motion raises a new issue of claim construction (D.I. 244, pp. 1 and 7 (section II)) are incorrect for the reasons set forth in Hanmi's November 1, 2012 letter to the Court, D.I. 242 at pp. 2-3. Similarly, any issues pertaining to the pretrial schedule have been addressed in Hanmi's letters to the Court, D.I. 242 and D.I. 251 (filed today).

Hanmi respectfully submits that its Motion to Amend should be granted for all of the reasons set forth therein, and briefly replies below to new points raised in AstraZeneca's Response.

II. The *Mylan* Case And Its Schedule Are Not Relevant

Despite the fact that the *Hanmi* and *Mylan* cases have not been consolidated for pretrial purposes, and without having ever brought a motion for consolidation, AstraZeneca improperly treats the *Hanmi* and *Mylan* cases as consolidated for trial purposes. D.I. 244 at pp. 1-3. This

again is an attempt by AstraZeneca to circumvent the April 2013 trial date confirmed by Judge Pisano,[1] even after AstraZeneca raised the *Mylan* case in scheduling discussions with the Court following the summary judgment hearing in June 2012. See D.I. 228 (Tarantino to Judge Bongiovanni re Pretrial Schedule). AstraZeneca's clear goal is to simply delay resolution of Hanmi's case and, accordingly, the potential entry of Hanmi's product into the market following the expiration of the 30-month FDA stay of approval on June 29, 2013.

Hanmi submits that the *Mylan* case – filed more than a year after Hanmi – and its schedule are not relevant to the present motion to amend or to the present case against Hanmi, for the reasons set forth in its recent submissions to the Court. *See* D.I. 242, pp. 4-5, and D.I. 251, pp. 2-3.

III. The Prior Litigation Record And Contentions Were Based On *AstraZeneca's* Asserted Claim Scope, As Encompassing Hydrates

At sections I-D to I-F, AstraZeneca's Response correctly points out that Hanmi's initial contentions did not raise the hydrated aspect of its esomeprazole strontium product as a non-infringement defense, that Hanmi's Motion No. 4 was limited to invalidity defenses based on "hydrates", and that the *Markman* submissions did not raise the issue of whether the claims of the patents-in-suit excluded hydrates from their scope. D.I. 244 at 4-6. Hanmi does not dispute these specific points, but they are not germane to resolution of Hanmi's motion, which is based on the *changed* litigation record as it stands today. *See* section IV below.

IV. Hanmi's Motion To Amend Conforms Its Contentions To The *Changed* Litigation Record

[1] The Court's July 5, 2012 Order scheduled the trial for April, 2013, on dates to be determined. See D.I. 230 (quoted without reference to the scheduled trial by AstraZeneca at D.I. 244, p. 3.) AstraZeneca's statement at D.I. 244, page 3,that there is no formal order in place is incorrect.

Hanmi seeks leave to amend to assert non-infringement of the asserted claims of the '504 and '192 patents-in-suit, based on *AstraZeneca's position* in opposition to Hanmi's Motion for Summary Judgment No. 4 (relating to invalidity due to hydrate scope), and the Court's August 30, 2012 Opinion (D.I. 233). Because AstraZeneca changed its position on the scope of the asserted claims during summary judgment briefing in an attempt to avoid Hanmi's invalidity challenges, equity demands that Hanmi should be permitted to show that its proposed tetrahydrate product does not infringe the claims.

AstraZeneca having brought suit and provided infringement contentions, Hanmi reasonably believed that AstraZeneca was asserting the '504 and '192 patents to encompass Hanmi's tetrahydrate form of esomeprazole strontium salt. However, this reasonable premise has turned out to be incorrect, based on the Court's ruling denying Motion No. 4 and AstraZeneca's assertions in its opposition brief. As discussed below, this fundamental shift in the underlying premises of this litigation in light of the Court's decision and AstraZeneca's position – i.e., "hydrates" are not set forth in, and are not material to the claims, and therefore do not have to be described or enabled – results in hydrates being excluded from the scope of the asserted '504 and '192 patent claims. *See generally* D.I. 238-1 at pp. 1-12.

V. Hanmi Has Demonstrated Good Cause For The Amendment

The denial of Hanmi's Motion No. 4 on August 30th in view of AstraZeneca's position in its opposition, gave rise to the instant motion and proposed amendments. The issues raised by the motion and amendment were simply not ripe before then. Following analysis of the Court's Order (D.I. 233), appropriate research, client discussions, preparation of the proposed amendment and motion papers, Hanmi provided AstraZeneca with the proposed amendment on October 11th seeking consent. AstraZeneca sought additional time to advise Hanmi of its

position, and Hanmi filed its Motion on October 15th upon receipt of AstraZeneca's response. Under the circumstances, Hanmi acted with appropriate diligence.

Any arguments by AstraZenenca that Hanmi should have acted before the Court's denial of Hanmi's Motion No. 4 fail to take into account the express grounds which lead to the instant motion and proposed amendment. Hanmi submits that the good cause requirement of Local Patent Rule 3.7 has been met, for all of the reasons set forth in its detailed Memorandum supporting the motion to amend (D.I. 238-1). None of AstraZeneca's case authorities comport with the specific facts of this case.

VI. The Amendment Does Not Prejudice AstraZeneca

Contrary to AstraZeneca's arguments at D.I. 244, pp. 13-14, the proposed amendment will not impact the case schedule or the scope of discovery, or prejudice AstraZeneca.

With respect to non-infringement based on hydrate scope, AstraZeneca brought this upon itself, based on the positions it elected to take on the summary judgment record. *See* D.I. 238-1 at 4-5, summarizing AstraZeneca's positions in D.I. 253.

In terms of Hanmi's modest supplement to its invalidity defenses based on hydrates that were raised in Motion No. 4 (D.I. 238-1 at 13-14), Hanmi is merely conforming its present contentions (sent in draft to AstraZeneca on October 11, 2012) to the existing summary judgment record. This supplement directly responds to AstraZeneca's "later-developed technology" argument, raised for the first time on the summary judgment record – but not in AstraZeneca's prior responses to Hanmi's invalidity contentions. *See* section VII, *infra*. The case is now ripe for development of full expert reports on Hanmi's written description and nonenablement defenses based on hydrates, without prejudice to either party.

VII. Hanmi's Modest Supplement To Its Invalidity Defenses Based on Hydrates Responds To An Issue Not Previously Raised By AstraZeneca

Although Hanmi's Motion No. 4 was denied, AstraZenenca is incorrect in asserting that there has been any final adjudication on the merits with respect to Hanmi's defenses raised therein – that the asserted claims are invalid under 35 U.S.C. § 112, first paragraph, based on lack of enablement and lack of written description. *See* D.I. 244 at 15-17. As an initial matter, AstraZeneca misquotes the Court's ruling. The Court ***did not***, as AstraZeneca states, find that "'hydrates' are ***not*** material to the written description or enablement inquiry" (D.I. 244 at 15); rather, the Court simply stated that "Hanmi has not convinced the Court that "hydrates" are material to the written description or enablement inquiry" (D.I. 233 at 19). That ruling in no way equates, as AstraZeneca claims, to summary judgment in favor of it on this issue.

Moreover, denial of one party's motion for summary judgment on a claim or defense, preserves the issue for trial, especially where, as here, the Court found that "there exist factual issues that would preclude summary judgment in any event." D.I. 233 at 19-20. The Court retains the power to change matters adjudicated any time before entry of final judgment. *See Streber v. Hunter*, 221 F.3d 701, 737 (5th Cir. 2000). And, contrary to AstraZeneca's argument, the denial of a motion for summary judgment is not "law of the case." Absent certification, the denial of summary judgment is a non-appealable interlocutory order, not a final judgment, and has no *res judicata* effect. *See Paquin v. Fed. Nat. Mortg. Ass'n*, 20 F. Supp. 2d 94, 96 (D.D.C. 1998) (quotations omitted) ("denial of a motion for summary judgment does not constitute the law of the case because it does not purport to decide the factual question, it merely denies the motion because, in the court's then view, there were issuable facts. Such a denial merely postpones decision of any question; it decides none"); *Perez-Ruiz v. Crespo-Guillen*, 25 F.3d

40,42 (1st Cir. 1994) ("[i]nterlocutory orders . . . remain open to trial court reconsideration, and do not constitute the law of the case"); *In re Corrugated Container Antitrust Litig.*, 694 F.2d 1041, 1043 (5th Cir. 1992); 10A Charles A. Wright, et al., *Federal Practice & Procedure* § 2712 (3rd ed.2002) ("a denial of summary judgment is not a decision on the merits; it simply is a decision that there is a material factual issue to be tried").

AstraZeneca correctly notes that it filed no summary judgment motion on either of Hanmi's written description or enablement defenses. AstraZeneca incorrectly assumes that the Court entered summary judgment in its favor *sua sponte* (D.I. 244 at 15-16), when no such judgment exists. The Court's Opinion and Order plainly state that Motion No. 4 is denied, not that judgment is to be entered in favor of AstraZeneca. D.I. 233 at 20; D.I. 234. AstraZeneca's suggestion that summary judgment effectively was entered against Hanmi is incorrect. As with any denial of summary judgment, the matter remains ripe for trial upon full presentation of the evidence developed in discovery.

Hanmi's amendment supplementing its nonenablement defense based on hydrates directly responds to AstraZeneca's position on "later-developed technology" raised by AstraZeneca for the first time in its summary judgment opposition (D.I. 153), but not in its responses to Hanmi's invalidity contentions (*see* D.I. 244-5 at 46-49). Given that Hanmi had no notice that AstraZeneca planned to rely on such a position, Hanmi's modest amendment to its invalidity contentions at D.I. 239, pp. 84 ('504 patent) and 141 ('192 patent) – each of which refers back to pp. 24-26 responding to AstraZeneca's "later-developed technology" position – should be permitted as a matter of fundamental fairness.

VIII. Conclusion

Hanmi respectfully submits that its Motion to Amend Contentions should be granted.

Dated: November 14, 2012

Respectfully,

LITE DEPALMA GREENBERG, LLC

s/Mayra V. Tarantino
Allyn Z. Lite
Michael E. Patunas
Mayra V. Tarantino
Two Gateway Center, 12th Floor
Newark, New Jersey 07102
Telephone: (973) 623-3000
Facsimile: (973) 877-3872
alite@litedepalma.com
mpatunas@litedepalma.com
mtarantino@litedepalma.com

Of Counsel:
SUGHRUE MION, PLLC
Mark Boland
Michael R. Dzwonczyk
Renita S. Rathinam
2100 Pennsylvania Ave., NW
Washington, DC 20037-3213
Telephone: (202) 293-7060
Facsimile: (202) 293-7860
mboland@sughrue.com
mdzwoncyzk@sughrue.com
rrathinam@sughrue.com

SUGHRUE MION, PLLC
John B. Scherling
4250 Executive Square
Suite 900
La Jolla, CA 92037
Telephone: (858) 795-1180
Facsimile: (858) 795-1199
jscherling@sughrue.com

Attorneys for Defendants and Counterclaim-Plaintiffs, Hanmi USA, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd., and Hanmi Holdings Co., Ltd.

CERTIFICATE OF SERVICE

I hereby certify that on November 14, 2012, I caused a copy of the foregoing HANMI'S REPLY IN SUPPORT OF ITS MOTION TO AMEND ITS CONTENTIONS to be served on counsel for AstraZeneca through the Court's ECF system and by email.

s/Mayra V. Tarantino
Mayra V. Tarantino